

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8488

Bartle, C.J.

June 30, 2010

Debra Sherlock ("Ms. Sherlock" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen R. Peters, M.D. Based on an echocardiogram dated May 18, 2001, Dr. Peters attested in Part II of Ms. Sherlock's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$518,044.³

2. (...continued)
describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is
(continued...)

In the report of claimant's echocardiogram, Dr. Peters stated that claimant had moderate mitral regurgitation. Dr. Peters, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2003, the Trust forwarded the claim for review by James W. Mathewson, M.D., one of its auditing cardiologists. In audit, Dr. Mathewson concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Mathewson explained that:

In the [parasternal] long axis and apical 4 chamber views, there is no visible mitral regurgitation in moving images. Only on freeze frame images in the apical 4 chamber view can one see a small, narrow jet of regurgitation. Although the [left ventricle] and [left atrium] on gross inspection appear to be mildly dilated, the cause of this

3. (...continued)
diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

dilation is not the trace-to-mild degree of mitral regurgitation found in this study.

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Sherlock's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁴ In contest, claimant argued that the auditing cardiologist's finding was inconsistent with the finding of Dr. Peters, who performed claimant's echocardiogram under the Trust's Screening Program.⁵ In addition, claimant submitted that the auditing cardiologist used a method for determining the level of mitral regurgitation that was not prescribed by the Settlement Agreement because he did not measure the RJA or the LAA.

The Trust then issued a final post-audit determination, again denying Ms. Sherlock's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Sherlock's claim.

5. See Settlement Agreement § IV.A.I.a. (Screening Program established under the Settlement Agreement).

show cause why Ms. Sherlock's claim should be paid. On September 27, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3992 (Sept. 27, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 30, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of the Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Sherlock repeats the arguments she made in contest; namely, that the auditing cardiologist, Dr. Mathewson, improperly "eyeballed" the level of her mitral regurgitation and that because her echocardiogram was performed by a cardiologist who participated in the Trust's Screening Program, the auditing cardiologist is disagreeing with the Trust's own physician.

In response, the Trust argues that the audit of Ms. Sherlock's claim was conducted in accordance with the Settlement Agreement and the Audit Rules. The Trust also asserts that the auditing cardiologist is not required to provide specific measurements regarding claimant's level of mitral regurgitation. Moreover, the Trust contends that claimant has not established that a reasonable medical basis exists to support her claim.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no

reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante stated that:

Visually, no mitral regurgitation could be found on color flow evaluation in the parasternal long axis view. Visually, only mild mitral regurgitation was noted in the apical two chamber and apical 4 chamber views. I digitized those cardiac cycles in the apical 4 chamber and apical two chamber views in which the mitral regurgitation appeared most severe. I then planimetered the RJA and LAA in those cardiac cycles in which the mitral regurgitation jet appeared the greatest. I found that the RJA/LAA ratio was less than 15% in those cardiac cycles in which the mitral regurgitation appeared most severe. Most of the cardiac cycles demonstrated RJA/LAA ratios less than 10%. The RJA/LAA ratio never came close to 20%. I was unable to determine how Dr. Peters was able to find moderate mitral regurgitation on this study.

Dr. Vigilante further stated that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest the specific analysis provided by the auditing cardiologist or the Technical Advisor. Claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34. Ms. Sherlock rests only on the attesting physician's check-the-box diagnosis on her Green Form and the report of her echocardiogram. Ms. Sherlock does not

refute or respond to the determinations of Dr. Mathewson or Dr. Vigilante that, at best, only mild mitral regurgitation was visible in the apical views. Mere disagreement without identification of specific errors by the auditing cardiologist or the Technical Advisor is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's argument concerning the required method for evaluating a claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." PTO No. 2640 at 15 (Nov. 14, 2002). Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.⁷

7. Claimant's argument also fails because the Technical Advisor, although not required to, made specific measurements of claimant's level of mitral regurgitation, which further establish (continued...)

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of her claim for Matrix Benefits was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for an echocardiogram performed in the Screening Program is a limited amount of medical services or cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of

7. (...continued)
that claimant is not entitled to Matrix Benefits.

the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Sherlock's claim for Matrix Benefits.